

CLINICAL TRIALS @ UCI

Clinical trials are research studies that involve people. It tests if a new treatment is safe and effective to prevent and manage a disease.

BASIC & TRANSLATIONAL RESEARCH



Cancer Center researchers collaborate to perform basic cancer research to understand how cancer cells differ from normal cells and to provide answers on how cancer cells develop, grow and spread.



Through this work, promising molecules, gene targets or biomarkers are discovered, which then move to translational research for further testing of potential drugs for cancer treatment.



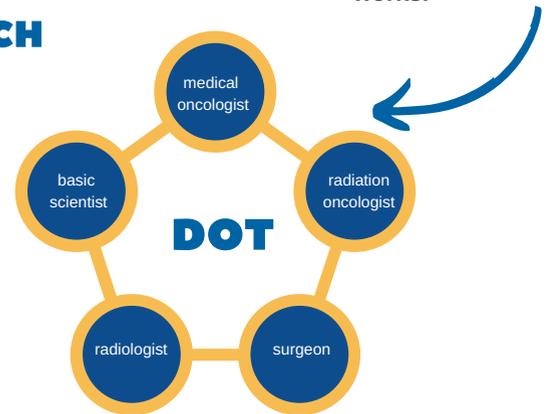
Target cells or tissues are first tested in vitro (meaning "in glass") and then in vivo ("in living organisms") to collect information about the drug works.

CLINICAL RESEARCH

Promising drugs are filed with the Food and Drug Administration before entering a clinical trial to be tested on cancer patients.

Before a clinical trial can begin, it is rigorously reviewed at several levels including:

- Multidisciplinary teams of doctors, surgeons, and scientists, called Disease-Oriented Teams (DOTs), ensure trials are of high scientific quality and importance.
- Institutional Review Board assures the safety and welfare of participants are protected.



FOUR PHASES OF CLINICAL TRIALS



PHASE 1

Phase 1 trials find the best dose of a new treatment with the fewest side effects.

- Tested in a small group of volunteers: 15 to 20
- Designed to decide how a new treatment should be given
- To see how the new treatment affects the human body and fights cancer
- Can take several months to complete



PHASE 2

Phase 2 trials continue evaluating safety.

- Tested in larger groups of volunteers: 25 to 100
- Designed to determine if a drug or treatment has an effect on a certain cancer
- Can take about two years to complete



PHASE 3

Phase 3 trials compare a new drug or treatment to standard-of-care.

- Tested in a much larger group of volunteers: 100s to several 1000
- Trials assess the side effects of each drug or treatment and evaluate which works better
- Patients are randomly assigned to receive either the new treatment or the best existing treatment
- Volunteers are followed for several years



PHASE 4

Phase 4 trials, the final phase, asks new questions about standard treatments.

- Begins after a drug or treatment is approved by the FDA and made available to the public
- Trials evaluate the long-term benefits, side effects and how well the drug works when used more widely
- Data collected on the drug or treatment's risks, benefits and optimal uses

Phase 1-3: 10-15 years

Through clinical research, we are able to gain answers and insights about the effectiveness and safety of drugs and other medical therapies. These groundbreaking advancements in science have only been possible due to participation of volunteers (sick or healthy).

WHY PARTICIPATE IN CLINICAL TRIALS?

HOW DO I GET INVOLVED?

cancer.uci.edu



To determine if you are eligible for any cancer clinical trials at UCI, please call 877-UC-STUDY (877-827-8839) or email ucstudy@uci.edu.

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UCI Health

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A Comprehensive Cancer Center
Designated by the National Cancer Institute